

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS F O Box 1450 Alexandria, Virginia 23313-1450 www.uspilo.gov

| APPLICATION NO.                                       | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|------------------|----------------------|---------------------|------------------|
| 09/731,318  | 12/06/2000       | Steve Paboojian      | PAT053246-US-CNT02  | 1028             |
| 1095<br>NOVARTIS                                      | 7590 03/14/201   | EXAMINER             |                     |                  |
| CORPORATE   | INTELLECTUAL PRO | MENDOZA, MICHAEL G   |                     |                  |
| ONE HEALTH PLAZA 101/2<br>EAST HANOVER, NJ 07936-1080 |                  |                      | ART UNIT            | PAPER NUMBER     |
|   |                  |                      | 3734                |                  |
|   |                  |                      |                     |                  |
|   |                  |                      | MAIL DATE           | DELIVERY MODE    |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

|                 | 1 4 11 11 1      | _ |  |
|-----------------|------------------|---|--|
| Application No. | Applicant(s)     |   |  |
| 09/731,318      | PABOOJIAN ET AL. |   |  |
| Examiner        | Art Unit         | _ |  |
| MICHAEL MENDOZA | 3734             |   |  |

|  | MICHAEL MENDOZA   | 3734 |  |  |  |  |  |
|--|---|------|--|--|--|--|--|
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |      |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE & MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extension of time may be available under the provision of 37 CFR 1136(a). In no weet, however, may a reply be timely filed after SIX (6) MONTHS from the malting date of this communication.  - INC period to reply is specified above, the readment estudy period will exply and will expire SIX (6) MONTHS from the malting date of this communication.  - INC period to reply is specified above, the readment estudy period will expire SIX (6) MONTHS from the malting date of this communication.  - INC period to reply is specified above, the readment estudy period will expire SIX (6) MONTHS from the malting date of this communication.  - Any reply received by the Office later than three months after the malting date of this communication, even if timely filed, may reduce any earned patent from adjustment. See 37 CFR 1704(b). |   |      |  |  |  |  |  |
| Status   |   |      |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 22 <u>December 2011</u> .  2a) This action is <b>FINAL</b> . 2b) This action is non-final.  3) An election was made by the applicant in response to a restriction requirement set forth during the interview on the restriction requirement and election have been incorporated into this action.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |      |  |  |  |  |  |
| Disposition of Claims  |   |      |  |  |  |  |  |
| 5) ⊠ Claim(s) 1-4.13-22 and 31-34 is/are pending in the application.  5a) Of the above claim(s)  |   |      |  |  |  |  |  |
| Application Papers   |   |      |  |  |  |  |  |
| 10) The specification is objected to by the Examiner.  11) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |      |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |      |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some *c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received.   |   |      |  |  |  |  |  |
| Attachment(s)  |   |      |  |  |  |  |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper Notich Tate  | 4) Interview Summar Paper No(s)/Mail I  5) Notice of Informal | Date |  |  |  |  |  |

Application/Control Number: 09/731,318 Page 2

Art Unit: 3734

#### DETAILED ACTION

### Response to Arguments

 Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has amended independent claim 1 to include "only". The amendment changes the scope of the claim requiring new consideration.

### Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Any claim containing a negative limitation which does not have basis in the original disclosure should be reject under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. There is no written description in the specification reciting that the powdered medicament exits the cavity only through the top end.

#### Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Application/Control Number: 09/731,318 Page 3

Art Unit: 3734

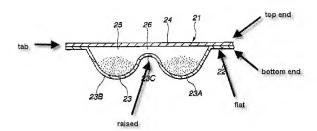
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki
   EP 1106196.
- 7 Ohki teaches a system for aerosolizing a powdered medicament the system comprising: a dry powder inhaler (fig. 18) and a receptacle (fig. 17), the receptacle comprising: a receptacle body that defines a sealed cavity containing powdered medicament (fig. 17), wherein the receptacle body has a top end (24) and a bottom end (22), wherein the bottom end (22) of the receptacle body includes a raised central region (23c) that extend upwardly into the cavity (fig. 17), and wherein the receptacle is shaped and adapted to be insertable into the dry powder inhaler and wherein the raised central region is shaped to facilitate extraction of the powdered medicament when air or another gas is drawn through the cavity (fig. 18) so that the powdered medicament exits the cavity through the top end (through 11b). It should be noted that Ohki fails to teach wherein the powdered medicament exits the cavity **only** through the top end. However. the system of Ohki is fully capable of performing the limitation. When only the top end (22) of Okhi is pierced, the resulting openings in the top end would still provide fluid communication to channels 10A and 11B allowing air to draw the powdered medicament out of the receptacle.
- Ohki teaches the system of claim 1, wherein the receptacle body further
  comprises at least one curved wall that in combination with the raised central region
  forms a generally semi-toroidal geometry in the cavity (fig. 16); wherein a portion of the

Application/Control Number: 09/731,318

Art Unit: 3734

bottom end is flat in geometry; wherein the receptacle body further includes a tab extending from the cavity.



Allowable Subject Matter

- 9. Claims 13-22 and 31-34 are allowable over the prior art of record.
- 10. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach a method for aerosolizing a powdered medicament, the method comprising: inserting a bottom end of an extraction tube into the cavity such that the bottom end of the extraction tube is aligned with a raised central region and is spaced above the bottom end of the receptacle; forming vents in the top end of the receptacle about a periphery of the cavity; and in combination with other method steps of the independent claim.

Application/Control Number: 09/731,318 Page 5

Art Unit: 3734

#### Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 10:00 a.m. - 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, *please contact* the examiner's supervisor, GARY JACKSON, *at* (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/731,318

Art Unit: 3734

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Mendoza /M. M./ Examiner, Art Unit 3734 2/15/2012

/Gary Jackson/ Supervisory Patent Examiner Art Unit 3734